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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0251]

Draft Guidance for Industry, Food and Drug Administration Staff, and Food and Drug Administration-Accredited Third-Parties: Requests for Inspection by an Accredited Person Under the Inspections by Accredited Persons Program Authorized by the Medical Device User Fee and Modernization Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Requests for Inspection by an Accredited Person Under the Inspections by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002." Section 201 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) authorizes FDA-accredited third parties (accredited persons or APs) to conduct inspections of manufacturers of class II and class III devices who meet certain eligibility criteria as defined by the statute. This draft guidance document describes the establishment eligibility criteria and the process for establishments to follow when requesting FDA's approval to have an AP conduct an inspection of their establishment instead of FDA under the new inspections by accredited persons program (AP program).

DATES: Submit written or electronic comments on this draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. Submit

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comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled "Requests for Inspection Under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on the guidance and collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance and collection of information to: *http://www.fda.gov/dockets/ecomments*. Identify all comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For medical device issues: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Road, Rockville, MD 20850 301–594–4692

For biologics issues: Carol Rehkopf, Center for Biologics Evaluation and Research (HFM–650) Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852 301–827–6202

SUPPLEMENTARY INFORMATION:

I. Background

MDUFMA (Public Law 107–250) added a provision in section 704(g) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374(g)) to permit third-party inspections of eligible establishments who market class II or class III devices in the United States and who also market or plan to market such devices in foreign countries. The new law also defines the qualifying criteria that a manufacturer must meet in order to participate in the AP program (section 704(g)(6)(A) of the act). This guidance will help manufacturers determine whether they are eligible to participate in this inspectional program and identifies the information manufacturers should submit to the agency when requesting permission to use an AP.

The AP program generally enables manufactures to better manage their inspection schedules since they will schedule the AP inspections themselves, provided FDA has approved their request to use an AP. Eligible firms, however, remain subject to inspections by FDA (section 704(g)(9) of the act). The program is voluntary; no manufacturer is required to participate, whether domestic or foreign.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on inspection requests under the AP program authorized by section 201 of MDUFMA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Comments

Interested parties may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

To receive "Requests for Inspection under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002" by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1532 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of cleared submissions, approved applications, and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Internet may be accessed at *http://www.fda.gov/cdrh*. A search capability for

all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html.* Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets.*

V. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Requests for Inspection under the Inspection by Accredited Persons Program

Description: Section 201 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) amends section 704 of the Federal Food, Drug, and Cosmetic Act (the act) by adding paragraph (g). This amendment authorizes FDA to establish a voluntary third party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. Under this new Inspection by Accredited Persons Program (AP program), such manufacturers may elect to have third parties that have been accredited by FDA (accredited person or AP) conduct some of their inspections instead of FDA.

The AP program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such manufacturers may need current inspections of their establishments to operate in global commerce.

The applicant must submit the following information in support of a request for approval to use an AP:

1. Information that shows that the applicant "manufactures, prepares, propagates, compounds, or processes" class II or class III medical devices.

2. Information that shows that the applicant markets at least one of the devices in the United States.

3. Information that shows that the applicant markets or intends to market at least one of the devices in one or more foreign countries and one or both of the following two conditions are met as follows:

a. One of the foreign countries certifies, accredits, or otherwise recognizes the AP the applicant has selected as a person authorized to conduct inspections of device establishments, or

b. A statement that the law of a country where the applicant markets or intends to market the device recognizes an inspection by the FDA or by the AP.

4. Information that shows that the applicant's most recent inspection performed by FDA, or by an AP under this program, was classified by FDA as either "No Action Indicated (NAI)" or "Voluntary Action Indicated (VAI)"; and

5. A notice to FDA requesting clearance (approval) to use an AP, and identifying the AP the applicant selected.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
100	1	100	15	1,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP program. In addition, 40 percent of the domestic firms do not export devices and therefore are not eligible for the AP program. Also 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates that there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion in the AP program. Based on informal communications with

industry, FDA estimates that approximately 100 of these manufacturers may apply to use an AP in any given year.

Dated: 5/27/04

May 27, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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